

Atty Dkt. No.: LIFE-043
USSN: 10/055,788

REMARKS

Claim 1-54 were pending in the application. Claims 1-46 were examined and claims 47-65 were withdrawn from consideration.

Claims 1-46 were rejected.

Claims 1, 7, 16, 25 and 35 have been amended to specify the inclusion of hemoglobin. Support for this amendment may be found in the specification and the originally filed claims, for example at page 13, paragraph 45 and original claims 10, 15 and 19. The phrase "capable of aggregating in plasma" has also been cancelled from claims 1, 7, 25 and 35 and these claims have been amended to specify "plasma aggregatable particles".

Claim 16 has been further amended to specify that the particles are present in a suspension. Support for this amendment may be found, for example, at page 9, paragraph [0032] and originally filed claim 32.

Claim 25 has been further amended with respect to step (c) to specify that the control solution is introduced into the coagulation test.

Claim 5 has been rejected for because "said calcium ion source" lacks antecedent basis. Claim 5 has been amended to specify "calcium ion" which finds antecedent basis from the claim from which it depends.

Claims 1-2, 4-9, 11-14, 16-18 and 20-46 are pending after the entry of the amendments made herein.

Paragraph [0097] has been amended to replace the words "comprise" and "comprising" with "include" and "including".

In view of the above amendments and the following remarks, the Examiner is respectfully requested to withdraw the rejections and allow Claims 11-2, 4-9, 11-14, 16-18 and 20-46, the only claims pending in this application.

As no new matter has been added by the above amendments, the Applicants respectfully request the entry thereof.

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OBJECTION TO THE DISCLOSURE

The Abstract has been objected to because of the inclusion of legal phraseology such as "comprise" and "comprising". The Abstract has been amended to replace the words "comprise" and "comprising" with "include" and "including". Accordingly, the Applicants respectfully request that this rejection be withdrawn.

REJECTION UNDER 35 U.S.C. §112, SECOND PARAGRAPH

Claims 1-15, 19, 23 and 25-46 have been rejected under 35 U.S.C. §112, second paragraph as being indefinite.

Specifically, claims 1, 7, 25 and 35 have been rejected for the phrase "capable of". These claims have been amended to remove the phrase "capable of". The claims have been amended to specify plasma aggregatable particles. Accordingly, the Applicants respectfully request that this rejection be withdrawn.

Claim 5 has been rejected because "said calcium ion source" lacks antecedent basis. Claim 5 has been amended to specify "calcium ion" which finds antecedent basis from the claim from which it depends. Accordingly, the Applicants respectfully request that this rejection be withdrawn.

Claim 15 has been rejected because "said aggregation enhancer" lacks antecedent basis. This claim has been cancelled. Accordingly, the Applicants respectfully request that this rejection be withdrawn.

Claim 19 has been rejected because "said aggregation enhancer" lacks antecedent basis. This claim has been cancelled. Accordingly, the Applicants respectfully request that this rejection be withdrawn.

Claim 23 has been rejected because "said suspension" lacks antecedent basis. Claim 16, from which claim 23 depends, has been amended to specify a suspension. Accordingly, the Applicants respectfully request that this rejection be withdrawn.

Claim 25 has been rejected because it recites both the control solution and the plasma. Claim 25 has been amended with respect to step (c) to specify that the control solution is introduced into the coagulation test. Accordingly, the Applicants respectfully request that this rejection be withdrawn.

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REJECTION UNDER 35 U.S.C. §102(b)

Claims 1-2, 4-7, 12-14, 16, 18 20-22, 25-26, 32-36 and 43-44 have been rejected under 35 U.S.C. §102(b) as being anticipated by Collier.

Claims 1, 7 and 16, and the claims that depend therefrom, have been amended to specify that the compositions include hemoglobin. However, Collier does not teach such a composition, e.g., Collier does not teach a composition that includes hemoglobin. As such, Collier fails to anticipate the subject claims for at least this reason.

Claim 25 specifies a method that include the steps of forming a control solution and introducing that solution to a coagulation test and claim 35 specifies combining citrated plasma, particles and a solution of calcium ions to a coagulation test. Accordingly, each of these claims specifies a step of introducing the specified composition to a coagulation test. However, Collier does not teach the preparation of a composition and a subsequent step of introducing that composition to a coagulation test. As such, Collier fails to anticipate the subject claims for at least this reason.

For at least the reasons described above, the Applicants respectfully submit that Claims 1-2, 4-7, 12-14, 16, 18 20-22, 25-26, 32-36 and 43-44 are not anticipated under 35 U.S.C. §102(b) by Collier. As such, the Applicants respectfully submit that request that this rejection be withdrawn.

Claims 1, 5, 7, 25-27, 29, 32, 35-37, 39 and 44 have been rejected under 35 U.S.C. §102(b) as being anticipated by Volger et al.

Claims 1 and 7, and the claims that depend therefrom, have been amended to specify that the compositions include hemoglobin. However, Volger, et al. do not teach such a composition, e.g., Volger, et al. do not teach a composition that includes hemoglobin. As such, Volger, et al. fail to anticipate the subject claims for at least this reason.

Claim 25 specifies a method that includes the steps of forming a control solution and introducing that solution to a coagulation test and claim 35 specifies combining citrated plasma, particles and a solution of calcium ions to a coagulation test. Accordingly, each of these claims specifies a step of introducing the specified composition to a coagulation test. However, Volger et al. do not teach the preparation of a composition and a subsequent step of introducing that composition to a coagulation test. As such, Volger et al. fail to anticipate the subject claims for at least this reason.

For at least the reasons described above, the Applicants respectfully submit that Claims, 5, 7, 25-27, 29, 32, 35-37, 39 and 44 are not anticipated under 35 U.S.C. §102(b) by Volger et al. As such, the Applicants respectfully submit that request that this rejection be withdrawn.

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Rejection under 35 U.S.C. §103(a)

Claims 30-31, 40 and 46 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Volger et al.

As noted above, Volger et al. fail to teach or even suggest all the claimed limitations of claims 25 and 55, from which these claims depend.

More specifically, independent claim 25, from which claims 30 and 31 depend, specifies combining calcium ions and plasma aggregatable particles with plasma to form a control composition and introducing this control composition to a coagulation test. However, Volger et al. fail to teach or even suggest forming a control composition by combining plasma aggregatable particles, calcium ions and plasma and introducing this control composition to a coagulation test and in fact does not teach or suggest preparing any composition and subsequently introducing it to a coagulation test. Independent claim 35, from which claims 40 and 46 depend specifies combining plasma aggregatable particles, calcium ions and citrated plasma and introducing this combination of components to a coagulation test. However, Volger et al. fail to teach or even suggest combining plasma aggregatable particles, calcium ions, citrated plasma and introducing this combination of components to a coagulation test and in fact does not teach or suggest preparing any composition and subsequently introducing it to a coagulation test.

Accordingly, for at least the reasons described above, a proper *prima facie* case of obviousness cannot be sustained. As such, the Applicants respectfully request that this rejection be withdrawn.

Claims 3, 10, 15, 19 and 41-42 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Coller in view of Lewis et al. Claim 3, 10, and 15 have been cancelled and analogous subject matter specified therein has been incorporated into claims 1, 7 and 16. Accordingly, the Applicants will respond to this rejection with respect to claims 1, 7, 16 and 41-42.

The Applicants respectfully submit that there is no motivation in either of these references to modify the invention of Coller to make the invention as claimed in the present application. More specifically, there is no motivation to modify the invention of Coller to include, an aggregation enhancer, let alone hemoglobin.

Coller teaches the agglutination of small polymeric beads coated with a glycoprotein IIb/IIIa ligand such as fibrinogen when the beads are contacted with whole blood containing platelets with glycoprotein IIb/IIIa receptors that are not blocked. (see Abstract for example) Coller teaches that failure

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to agglutinate indicates that blockade of the GPIIb/IIIa receptor has been achieved. In other words, the beads of Coller agglutinate in the presence of unblocked IIB/IIIA receptors. Coller teaches that "platelet mediated agglutination of the solid surface results when the GPIIb/IIIa receptors on the surface of platelets bind...with GPIIb/IIIa ligands bound to the solid surfaces." (see for example col. 4, lines 62-65) That is, Coller is concerned with measuring the degree of GPIIb/IIIa ligand/ receptor binding. Accordingly, it is not necessary to provide a component to increase or enhance aggregation of the beads, as the degree of aggregation is used as an indication of platelet IIB/IIIA receptor blockage. Accordingly, there is no motivation to modify the invention of Coller to include a bead aggregation enhancer as such may compromise the results obtained from the Coller invention.

Accordingly, for at least the reason described above, a proper *prima facie* case of obviousness cannot be made. As such, the Applicants respectfully request that this rejection be withdrawn.

Claims 11, 23 and 45 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Coller in view of Jacobs et al.

Claims 11, 23 and 45 depend from claims 7, 16 and 35, respectively. As noted above, claims 7 and 16, and the claims that depend therefrom, have been amended to specify that the compositions include hemoglobin. However, Coller does not teach or suggest such a composition, e.g., Coller does not teach a composition that includes hemoglobin. As noted above, claim 35 specifies combining citrated plasma, plasma aggregatable particles and a solution of calcium ions and introducing the combination to a coagulation test. However, Coller does not teach the preparation of any composition and a subsequent step of introducing a composition to a coagulation test. Accordingly, Coller does not teach each and every element of claims 11, 23 and 45. As Jacobs et al is cited solely for teaching antifreeze, Jacobs et al. fails to make up for the deficiencies of Coller. Accordingly, for at least the reasons described above, a proper *prima facie* case of obviousness cannot be made. As such, the Applicants respectfully request that this rejection be withdrawn.

Objections

The Examiner has indicated that claims 28 and 38 would be allowable if rewritten to overcome the rejections under 35 U.S.C. 112, second paragraph and to include all of the limitations of the base claims and any intervening claims. The Applicants thank the Examiner for the indication of allowance.

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CONCLUSION

In view of the remarks, this application is considered to be in good and proper form for allowance and the Examiner is respectfully requested to pass this application to issue.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§1.16 and 1.17 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 50-0815, reference no. LIFE-043.

Respectfully submitted,
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Date: 10/21/03

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